

Interview Summary	Application No. 10/029,016	Applicant(s) CELESTE ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

All participants (applicant, applicant's representative, PTO personnel):

(1) David S. Romeo.

(3) Leslie McDonell.

(2) Mary K. Ferguson.

(4) _____.

Date of Interview: 11 August 2005.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Draft amendment to the claims.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

David S. Romeo
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussed enablement of the claimed methods with respect to the genus of variant BMP-11s encompassed by the hybridization language. Inserting the specific hybridization conditions would overcome § 112, second paragraph, issues, but may not overcome the enablement issues under § 112, first paragraph. Enablement does not necessarily hinge on the recitation of a structural limitation in combination with a functional limitation, as indicated by the factors set forth in *In re Wands*. Applicants indicated they would file a RCE in order to get any newly proposed or amended claims considered, and the examiner agreed to further consider the enablement issues in such an RCE.



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TO

Name: David S. Romeo, Patent Examiner Date: August 11, 2005
Company: United States Patent and Trademark Office
Fax Number: 571-273-0890
Phone Number: 571-272-0890
Subject: In re Application of: CELESTE et al.
U.S. Patent Application No. 10/029,016
Filed December 20, 2001
Group Art Unit: 1647
Confirmation No: 4438

Confirmation Copy to Follow: NO

Total Pages (including cover): 8

FROM

Name: Mary K. Ferguson
Phone Number: 617-452-1618

Verified by: M. Fitch 1671
Our File No.: 08702.0051-02000

MESSAGE

In preparation for our telephone conference today.

If there is a problem with this transmission, notify sender at the number above.

This facsimile is intended only for the individual to whom it is addressed and may contain information that is privileged, confidential, or exempt from disclosure under applicable law. If you have received this facsimile in error, please notify the sender immediately by telephone (collect), and return the original message by first-class mail to the above address.

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AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-24. (Canceled).

25. (Currently amended) A method of promoting the survival of neuronal cells in a mammal comprising administering to the mammal ~~a therapeutically effective amount of~~ a BMP-11 polypeptide in an amount effective to promote the survival of neuronal cells, wherein the BMP-11 polypeptide comprises an amino acid sequence encoded by a nucleotide sequence chosen from:

- (i) nucleotides 778 to 1083 of SEQ ID NO:10;
- (ii) ~~nucleotide sequences that encode~~ a nucleotide sequence that encodes the same amino acid sequence as nucleotides 778 to 1083 of SEQ ID NO:10; ~~and~~ or
- (iii) ~~nucleotides that hybridize under stringent conditions with the nucleotide sequences of (i) or (ii) and encode a protein having BMP-11 activity in an osteoinduction assay~~ a nucleotide sequence that hybridizes under stringent conditions with the nucleotide sequence of (i) or (ii) and encodes a protein that promotes the survival of neuronal cells, wherein the stringent conditions comprise the steps of:
 - (a) hybridizing at 65°C in 5x SSC, 0.1% SDS, 5x Denhardt's, 100 ug/ml salmon sperm DNA; and

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(b) washing at 65°C in 0.1x SSC, 0.1% SDS,

thereby promoting the survival of neuronal cells in the mammal.

26. (Currently amended) A method of promoting the survival of neuronal cells in vitro comprising administering to the cells ~~a therapeutically effective amount of a~~ BMP-11 polypeptide in an amount effective to promote the survival of neuronal cells, wherein the BMP-11 polypeptide comprises an amino acid sequence encoded by a ~~nucleotide sequence chosen from:~~

- (i) nucleotides 778 to 1083 of SEQ ID NO:10;
- (ii) ~~nucleotides sequences that encode~~ a nucleotide sequence that encodes the same amino acid sequence as nucleotides 778 to 1083 of SEQ ID NO:10; ~~and or~~
- (iii) ~~nucleotides that hybridize under stringent conditions with the nucleotide sequences of (i) or (ii) and encode a protein having BMP-11 activity in an osteoinduction assay~~ a nucleotide sequence that hybridizes under stringent conditions with the nucleotide sequence of (i) or (ii) and encodes a protein that promotes the survival of neuronal cells, wherein the stringent conditions comprise the steps of:

(a) hybridizing at 65°C in 5x SSC, 0.1% SDS, 5x Denhardt's,
100 ug/ml salmon sperm DNA; and

(b) washing at 65°C in 0.1x SSC, 0.1% SDS,

thereby promoting the survival of the neuronal cells ~~in the mammal.~~

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27. (Currently amended) A method for inducing neurite formation from a ~~neural progenitor~~ neuronal cell in a mammal comprising administering to the mammal ~~a therapeutically effective amount of~~ a BMP-11 polypeptide in an amount effective to induce neurite formation from the neuronal cell, wherein the BMP-11 polypeptide comprises an amino acid sequence encoded by a nucleotide sequence chosen from:

- (i) nucleotides 778 to 1083 of SEQ ID NO:10;
- (ii) ~~nucleotide sequences that encode~~ a nucleotide sequence that encodes the same amino acid sequence as nucleotides 778 to 1083 of SEQ ID NO:10; ~~and or~~
- (iii) ~~nucleotides that hybridize under stringent conditions with the nucleotide sequences of (i) or (ii) and encode a protein having BMP-11 activity in an osteoinduction assay~~ a nucleotide sequence that hybridizes under stringent conditions with the nucleotide sequence of (i) or (ii) and encodes a protein that promotes the survival of neuronal cells, wherein the stringent conditions comprise the steps of:

- (a) hybridizing at 65°C in 5x SSC, 0.1% SDS, 5x Denhardt's, 100 ug/ml salmon sperm DNA; and
- (b) washing at 65°C in 0.1x SSC, 0.1% SDS,

thereby inducing neurite formation in the mammal.

28. (Currently amended) A method for inducing neurite formation from a ~~neural progenitor~~ neuronal cell in vitro comprising ~~treating the neural cell in vitro with a~~

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~~therapeutically effective amount of a BMP-11 polypeptide administering to the cell a~~
BMP-11 polypeptide in an amount effective to induce neurite formation from the
neuronal cell, wherein the BMP-11 polypeptide comprises an amino acid sequence
encoded by a nucleotide sequence chosen from:

- (i) nucleotides 778 to 1083 of SEQ ID NO:10;
- (ii) ~~nucleotides sequences that encode~~ a nucleotide sequence that encodes
the same amino acid sequence as nucleotides 778 to 1083 of SEQ ID
NO:10; and or
- (iii) ~~nucleotides that hybridize under stringent conditions with the nucleotide~~
~~sequences of (i) or (ii) and encode a protein having BMP-11 activity in an~~
~~osteoidinduction assay~~ a nucleotide sequence that hybridizes under
stringent conditions with the nucleotide sequence of (i) or (ii) and encodes
a protein that promotes the survival of neuronal cells, wherein the
stringent conditions comprise the steps of:

(a) hybridizing at 65°C in 5x SSC, 0.1% SDS, 5x Denhardt's,

100 ug/ml salmon sperm DNA; and

(b) washing at 65°C in 0.1x SSC, 0.1% SDS,

thereby inducing neurite formation from the neuronal cell.

29-34. (Canceled)

35. (Currently amended) The method of any one of claims 25-32 25-28,
wherein the BMP-11 polypeptide comprises amino acids 7 to 108 of SEQ ID NO:11.

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36. (Currently amended) The method of any one of claims ~~25-32~~ 25-28, wherein the BMP-11 polypeptide comprises amino acids 1 to 109 of SEQ ID NO:11.

37. (Canceled)

38-40. (Canceled)

41. (New) A method of promoting the survival of neuronal cells in a mammal comprising administering to the mammal a BMP-11 polypeptide in an amount effective to promote the survival of neuronal cells, wherein the BMP-11 polypeptide comprises an amino acid sequence chosen from:

(i) amino acids 7 to 108 of SEQ ID NO:11; and

(ii) amino acids 1 to 109 of SEQ ID NO:11;

thereby promoting the survival of neuronal cells in the mammal.

42. (New) A method of promoting the survival of neuronal cells in vitro comprising administering to the cells a BMP-11 polypeptide in an amount effective to promote the survival of neuronal cells, wherein the BMP-11 polypeptide comprises an amino acid sequence chosen from:

(i) amino acids 7 to 108 of SEQ ID NO:11; and

(ii) amino acids 1 to 109 of SEQ ID NO:11;

thereby promoting the survival of the neuronal cells.

43. (New) A method for inducing neurite formation from a neuronal progenitor cell in a mammal comprising administering to the mammal a BMP-11

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polypeptide in an amount effective to induce neurite formation from the neuronal progenitor cell, wherein the BMP-11 polypeptide comprises an amino acid sequence chosen from:

- (i) amino acids 7 to 108 of SEQ ID NO:11; and
- (ii) amino acids 1 to 109 of SEQ ID NO:11;

thereby inducing neurite formation in the mammal.

44. (New) A method for inducing neurite formation from a neuronal progenitor cell in vitro comprising administering to the cell a BMP-11 polypeptide in an amount effective to induce neurite formation from the neuronal progenitor cell, wherein the BMP-11 polypeptide comprises an amino acid sequence chosen from:

- (i) amino acids 7 to 108 of SEQ ID NO:11; and
- (ii) amino acids 1 to 109 of SEQ ID NO:11;

thereby inducing neurite formation from the neuronal progenitor cell.

45. (New) The method of claim 41, wherein the BMP-11 polypeptide consists of amino acids 7 to 108 of SEQ ID NO:11.

46. (New) The method of claim 41, wherein the BMP-11 polypeptide consists of amino acids 1 to 109 of SEQ ID NO:11.

47. (New) The method of claim 42, wherein the BMP-11 polypeptide consists of amino acids 7 to 108 of SEQ ID NO:11.

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48. (New) The method of claim 42, wherein the BMP-11 polypeptide consists of amino acids 1 to 109 of SEQ ID NO:11.

49. (New) The method of claim 43, wherein the BMP-11 polypeptide consists of amino acids 7 to 108 of SEQ ID NO:11.

50. (New) The method of claim 43, wherein the BMP-11 polypeptide consists of amino acids 1 to 109 of SEQ ID NO:11.

51. (New) The method of claim 44, wherein the BMP-11 polypeptide consists of amino acids 7 to 108 of SEQ ID NO:11.

52. (New) The method of claim 44, wherein the BMP-11 polypeptide consists of amino acids 1 to 109 of SEQ ID NO:11.